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PATENT
512100-2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Klein et al.
U.S. Serial No.	:	09/936,503 1615
International Application No.	:	PCT/EP00/02042
International Filing Date	:	March 9, 2000
For	:	**TRANSDERMAL THERAPEUTIC SYSTEM AND PROCESS FOR ITS PRODUCTION**

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New York, New York 10151

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William F. Lawrence, Registration No. 28,029
Name of Applicant, Assignee or Registered Representative

Signature

December 17, 2001
Date of Signature

COMMUNICATION

Assistant Commissioner for Patents
Box PCT
Washington, D.C. 20231

Sir:

Enclosed for the Examiner's convenience is a copy of

the International Preliminary Examination Report in PCT/EP00/02042.

Respectfully submitted,

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By _____

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Frau Ahlers
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PATENT COOPERATION TREATY

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NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

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From the INTERNATIONAL BUREAU

To:

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Date of mailing (day/month/year) 01 October 2001 (01.10.01)	
Applicant's or agent's file reference 1999/109	**IMPORTANT NOTIFICATION**
International application No. PCT/EP00/02042	**International filing date** (day/month/year) 09 March 2000 (09.03.00)
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AU,CA,CN,JP,KR,NZ,PL,US

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

EP,BR,CZ,HU,IL,IN,MX,RU,TR,ZA

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

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Translation

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1999/109	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/02042	International filing date (*day/month/year*) 09 March 2000 (09.03.00)	Priority date (*day/month/year*) 18 March 1999 (18.03.99)
International Patent Classification (IPC) or national classification and IPC A61K 9/70		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06 October 2000 (06.10.00)	29 June 2001 (29.06.2001)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP00/02042

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☒ the international application as originally filed.

☒ the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages 1-7, filed with the letter of 06 October 2000 (06.10.2000),
pages _____, filed with the letter of _____.

☒ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-6, filed with the letter of 24 April 2001 (24.04.2001),
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig 1/2, 2/2, filed with the letter of 06 October 2000 (06.10.2000),
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations

1. This report makes reference to the following documents:

D1: WO-A-94/06419 (LOHMANN THERAPIE SYST. LTS; MUELLER WALTER (DE); ANHAEUSER DIETER), 31 March 1994 (1994-03-31)

D2: GB-A-845 841 (MEYER F.), 24 August 1960 (1960-08-24)

D3: US-A-4 879 119 (KONNO YUTAKA ET AL.), 7 November 1989 (1989-11-07).

2.1 Document D1, which is considered the closest prior art, discloses (see page 7, last paragraph - page 9, first paragraph) a flat administration form from which the subject matter of Claim 1 differs by the following aspects:

Although D1 may concern a transdermal therapeutic system, these are non-medical administration forms (see page 11, paragraph 2). According to D1, the substrate material must be selected from paper foil, nonwoven, textile or another absorbent material (see page 4, paragraph 1). Although an active substance is mentioned on page 1, an active substance in the

sense of a medicament must not necessarily be applied to the substrate. Claim 1 of D1 mentions "ingredients" but an auxiliary substance (penetration enhancer) is applied to the substrate in the only example. The active substances lidocaine, diphenylhydramine hydrochloride, Salbutamol, 5-fluoruracil, fentanyl and sexual hormones or gestagenes are not mentioned.

The subject matter of Claim 1 is therefore novel (PCT Article 33(2)).

2.2 The present invention can therefore be considered to address the problem of providing an alternative transdermal therapeutic system.

2.3 The solution to this problem, as proposed in Claim 1 of the present application, involves an inventive step (PCT Article 33(3)) for the following reasons:

D1 does not give any indication that it would be advantageous to prefer paper to another substrate (nonwoven, textile...). Moreover, it does not give any indication of formulating transdermal therapeutic systems (TTS) containing the active substances mentioned in Claim 1 with support materials.

D2 describes a transdermal therapeutic system containing an impervious backing layer (2), a pressure-sensitive fixing element (1), a deposit of active substance (4) and a matrix layer containing a solvent (6), the active substance depot being made of filter paper impregnated with an ethanolic active substance solution (Fig. 2 and Examples 2 and 3).

D3 describes a transdermal therapeutic system containing an impervious backing layer (1), a pressure-sensitive fixing element (3), a deposit of active substance (2) and a matrix layer (7) made of filter paper and impregnated with propylene glycol (Fig. 2; column 4, lines 19-28; and Claims 1 and 6).

The TTS described in D2 and D3 contain either a wick system (D2) or a heatable element (D3), and therefore represent very special TTS configurations. Those documents do not suggest processing the active substances mentioned in Claim 1 to produce these special TTS forms.

2.4 Claims 2 and 3 are dependent on Claim 1 and therefore also meet the PCT requirements for novelty and inventive step.

3. For the interpretation of the present Claim 4, please note Box VIII, item 1.

3.1 D1, which is considered the closest prior art, discloses (see Claim 6) a method for producing a flat administration form from which the subject matter of Claim 4 differs in that the administration form is a transdermal therapeutic system, the dosing medium must contain an active substance (D1 mentions "ingredients", and in the only example an auxiliary substance (penetration enhancer) is applied to the substrate) and the web-shaped material is paper.

The subject matter of Claim 4 is therefore novel (PCT Article 33(2))

3.2 The present invention can therefore be considered to

address the problem of devising a method for producing transdermal therapeutic systems which scatter less the quantities of active substance applied.

3.3 The solution to this problem, as proposed in Claim 4 of the present application, involves an inventive step (PCT Article 33(3)) for the following reasons:

D1 does not give any indication that the use of paper in preference to other web-shaped materials (nonwoven, textile) leads to less scattering of the quantities of active substance applied.

3.4 Claims 5 and 6 are dependent on Claim 4 and therefore likewise meet the PCT requirements for novelty and inventive step.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The subject matter of Claim 4 is not clear (PCT Article 6). The expression "in the conventional manner" does not have an accurately defined meaning and is interpreted to mean, "as already described in the prior art".

   Moreover, the subject matter for which protection is sought is not clearly defined with regard to the "scattering of the quantity of active substance applied under 2%". This statement attempts to define the subject matter in terms of the result to be achieved, but merely indicates the problem in question. The claim does not define the technical features required to achieve this result.

2. Point (d) of Claim 1 defines a "pressure-sensitive fixing element (16) for fixing the therapeutic system to the skin". However, it is not possible to recognise in Figure 2 any element for fixing the therapeutic system to the skin.

   The embodiment depicted in Figure 2 falls outside the present claims. This contradiction between the claims and the description raises doubts as to the subject matter for which protection is sought, and for this reason the claims are not clear (PCT Article 6).